



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,831	06/21/2006	Lene Moller	13323-105005	6753
65989 7590 09/13/2010				
KING & SPALDING				
1185 AVENUE OF THE AMERICAS				
NEW YORK, NY 10036-4003				
EXAMINER				
KIM, TAEYOON				
ART UNIT		PAPER NUMBER		
1651				
NOTIFICATION DATE		DELIVERY MODE		
09/13/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary

Application No.

10/562,831

Applicant(s)

MOLLER ET AL.

Examiner

Taeyoon Kim

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 19,21-24,27-30,33-39,41 and 111-113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,10,11,14,15,17,18,40,42,48-59,61-63,86-94 and 101-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/23/2009, 2/19/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5,10,11,14,15,17-19,21-24,27-30,33-42,48-59,61-63,86-94 and 101-113.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/2010 has been entered.

Applicant's amendment and response filed on 4/14/2010 has been received and entered into the case.

Claims 2, 4, 6-9, 12, 13, 16, 20, 25, 26, 31, 32, 43-47, 60, 64-85 and 95-100 are canceled, claims 111-113 are newly added, and claims 19, 21-24, 27-30, 33-39, 41 and 111-113 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 1, 3, 5, 10, 11, 14, 15, 17, 18, 40, 42, 48-59, 61-63, 86-94 and 101-110 have been considered on the merits. All arguments have been fully considered.

Information Disclosure Statement

The information disclosure statement filed 12/23/2009 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no copy for the listed references. It is not clear whether the list of related cases submitted by Applicant on 12/23/2009 is meant to be IDS. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any

missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5, 10, 11, 14, 15, 17, 18, 40, 42, 48-59, 61-63, 86-99 and 101-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noishiki (US 5,986,168) in view of Choi et al. (1999; of record), Della Valle et al. (US 4,851,521; of record) and Moore et al. (US 3,678,933; of record).

Noishiki teaches a prosthesis comprising one or more bioabsorbable substances insolubilized and/or immobilized in place by a physical method including thermal crosslinking, and excluding chemical reagents (see abstract).

Noishiki teaches the thermal crosslinking is carried out at 100-180° for 1-48 hours (col. 8, lines 13-14), and thus meets the limitation.

Noishiki teaches that the prosthesis can be a wound dressing or hemostats (col. 9, lines 17-21), and the prosthesis can be a sponge-like form, or the bioabsorbable substance itself can be a sponge-like material, and it can form by itself a prosthesis without a porous substrate (col. 3, lines 38-41; col. 5, lines 42-43).

Noishiki teaches that the bioabsorbable substances include gelatin and hyaluronic acid (HA) (col. 5, line 66 through col. 6, line 22).

Although Noishiki does not particularly teach gelatin and HA, it would have been obvious to a person of ordinary skill in the art to try gelatin and HA selected from the list of bioabsorbable substances taught by Noishiki since Noishiki teaches that the prosthesis can comprise one or more bioabsorbable substances, and the Examples of Noishiki disclose two such substances crosslinked physically together for the prosthesis of Noishiki.

Furthermore, Choi et al. teach a hemostatic composition of gelatin and HA (see entire document). Thus, a person of ordinary skill in the art would recognize the combination of gelatin and HA as taught by Choi et al. as a well known combination for hemostatic prosthesis by themselves, and would certainly try this combination for the prosthetic composition of Noishiki with a reasonable expectation of success.

With regard to the concentration of gelatin and HA in the claimed composition, it is considered that the concentration of each ingredient present in the composition of Noishiki is considered as a result-effective parameter that can be modified by routine experimentation to obtain desirable outcome of using the composition as hemostats and/or wound dressing.

Furthermore, Choi et al. teach the hemostatic composition comprising gelatin and HA with the concentration of each ingredient being in the range of the claimed invention. Choi et al. teach the ratio of gelatin to HA being 9:1, 7:3 or 5:5, which is interpreted as gelatin being 50 to 90% and HA being 10 to 50%. Therefore, the claimed percentage for gelatin being at most 60 to 85% is within the range of gelatin (50 to 90%) taught by Choi et al. Similarly, the claimed percentage for HA being at most 15 to 40% is within the range of HA (10 to 50%) taught by

Choi et al.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try the percentage of HA and gelatin taught by Choi et al. in the composition of Noishiki with a reasonable expectation of success.

Noishiki does not teach the derivative of HA or ester of HA (claim 3).

Della Valle et al. teach esters of HA or a salt thereof being used for medical use such as sponge materials (Example 42 in col. 50).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to substitute HA with HA ester or a salt thereof for the prosthetic composition of Noishiki since it is considered that HA ester is an art-recognized alternative or equivalent to HA.

Although Noishiki does not particularly teach that the hemostatic sponge being covered by a top sheet (claim 14), it is well known in the art that a surgical dressing or sponge employs a plastic film as a cover as Moore et al. teach the use of thin plastic film as a cover of surgical dressing or sponge (col. 1, lines 43-55).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the thin plastic film (cover) of Moore et al. in the sponge of Noishiki in view of Choi et al.

The skilled artisan would have been motivated to make such a modification because Moore et al. teach that the thin plastic film provides non-sticking, non-sliding surface and high rate of absorption (col. 1, lines 4-13).

The person of ordinary skill in the art would have had a reasonable expectation of success

in using the plastic film cover/laminate of Moore et al. in the sponge of Noishiki in view of Choi et al.

Although Noishiki in view of Choi et al. and Moore et al. do not particularly teach the cover being removable, it would have been obvious to a person of ordinary skill in the art to make composition separable.

M.P.E.P. §2144.04 states if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.

In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is "press fitted" and therefore not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.").

With regard to the limitation drawn to the composition of gelatin and HA being paste, flake or powder, it would have been obvious to a person of ordinary skill in the art to try gelatin-HA sponge into a powder or a paste for different applications. It is considered that the format of the composition as sponge, powder or paste is merely an optional choice known in the art, and a person of ordinary skill in the art would try different, identified and predictable options.

The Supreme Court recently states in *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007)

“The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was “obvious to try.” *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.” See also *M.P.E.P.* §2141.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651